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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/010,020 | 12/05/2001 | Gary B. Gordon | 10002431-4 | 5593 |

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AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P. O. Box 7599
Loveland, CO 80537-0599

EXAMINER

FORMAN, BETTY J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1634

DATE MAILED: 08/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/010,020 | GORDON, GARY B. | |
| | Examiner | Art Unit | |
| | BJ Forman | 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 June 2004 has been entered.

Status of the Claims

2. This action is in response to papers filed 1 June 2004 in which claims 11, 12, 14, 15, 18, 19, 22 and 25 were amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 31 March 2004, not reiterated below, are withdrawn in view of the amendments or Applicant's comments.

All of the arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection are discussed.

Claims 8-25 are under prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 8-13, 15-23 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al (U.S. Patent Application Publication No. 2002/0001803 A1, filed 20 July 1999).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 8, Smith et al disclose an array hybridization method comprising introducing a sample liquid into a reaction cell so that some of the interior volume is partially occupied by sample liquid and partially occupied by gas (i.e. the sample liquid within the cell incompletely fills the cell which would further be filled with air, ¶ 48 and Fig. 3) centrifuging said sample liquid by rotating said cell having a probe array so that centrifugal forces in excess of 1G (¶ 50, lines 6-16) urge the sample liquid against the array and agitating said sample liquid in the reaction cell during centrifugation so that said sample liquid moves relative to the array (¶ 50-52 and Claims 1-5).

Regarding Claim 9, Smith et al disclose the method wherein the agitation involves rotating the sample cell about an axis that is more orthogonal to than along said centrifugal force i.e. not perpendicular (Claim 5).

Regarding Claim 10, Smith et al disclose the method wherein said agitating involves periodically changing the direction of rotation about the agitation axis (¶ 50, lines 16-22).

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Regarding Claim 11, Smith et al disclose the method wherein the said centrifugation involves rotating said cell at a centrifuge rate greater than agitation rate (§ 50).

Regarding Claim 12, Smith et al disclose the method wherein the agitation involves rotating said sample cell about an axis ("x") that extends parallel to the axis of centrifugal force (28) (Fig. 3 and § 50).

Regarding Claim 13, Smith et al disclose the method wherein the array extends more orthogonal to centrifugal than along it so that the centrifugal forces use the sample liquid against the array (§ 50, lines 22-28 and Fig. 3).

Regarding Claim 15, Smith et al disclose the method wherein the sample liquid occupies at most half of the interior volume (Fig. 3).

Regarding Claim 16, Smith et al disclose a method comprising introducing a sample liquid into a reaction cell having a hybridization probe array so that some of the interior volume is partially occupied by sample liquid and partially occupied by gas (i.e. the sample liquid within the cell incompletely fills the cell which would further be filled with air, § 48 and Fig. 3) centrifuging said sample liquid by rotating said cell having a probe array so that centrifugal forces urge the sample liquid against the array and agitating said sample liquid in the reaction cell during centrifugation so that said sample liquid moves relative to the array (§ 50-52 and Claims 1-5) wherein the agitation involves rotating the sample cell about an axis that is more orthogonal to than along said centrifugal force i.e. not perpendicular (Claim 5).

Regarding Claim 17, Smith et al disclose the method wherein the agitation involves periodically changing the direction of rotation about an axis to define an agitation cycle (§ 50).

Regarding Claim 18, Smith et al disclose the method wherein the said centrifugation involves rotating said cell at a centrifuge rate greater than agitation rate (§ 50).

Regarding Claim 19, Smith et al disclose the method wherein the sample liquid occupies at most half of the interior volume (Fig. 3).

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Regarding Claim 20, Smith et al disclose a method comprising introducing a sample liquid into a reaction cell having a hybridization probe array so that some interior volume is partially occupied by sample liquid and partially occupied by gas (i.e. the sample liquid within the cell incompletely fills the cell which would further be filled with air, ¶ 48 and Fig. 3) centrifuging said sample liquid by rotating said cell having a probe array so that centrifugal forces urge the sample liquid against the array and rotating the cell about an agitation axis that is more parallel than orthogonal to the centrifugal force so that said sample liquid moves relative to the array (¶ 50-52; Fig. 3; and Claims 1-5).

Regarding Claim 21, Smith et al disclose the method wherein the agitation involves periodically changing the direction of rotation about an axis to define an agitation cycle (¶ 50).

Regarding Claim 22, Smith et al disclose the method wherein the said centrifugation involves rotating said cell at a centrifuge rate greater than agitation rate (¶ 50).

Regarding Claim 23, Smith et al disclose the method wherein the array (#20) extends more orthogonal to the centrifugal force (#28) than along it so that the centrifugal force urges the sample liquid against the array (Fig.3 and ¶ 50).

Regarding Claim 25, Smith et al disclose the method wherein the sample liquid occupies at most half of the interior volume (Fig. 3).

Response to Arguments

5. Applicant's intention to file a declaration under 37 C.F.R. 1.132 "stating that the invention claimed in the present application and disclosed but not claimed by Smith et al. was derived from the inventor for the present application" is acknowledged.

The rejection is maintained.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8-13, 15-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robbins et al (U.S. Patent No. 5,380,662, issued 10 January 1995).

Regarding Claim 8, Robbins et al teach a reaction cell (bottle) having a hybridization array (nucleic acid bolts on a membrane, Column 3, line 7-10) so that some interior volume is partially occupied by a sample liquid and partially occupied by gas (Fig. 4) wherein centrifugation (via rotational force, column 3, lines 43-47) of the sample liquid is by rotating the reaction cell whereby agitation of the sample during the centrifugation moves the sample relative to the array (Column 3, lines 4-57 and Abstract).

Robbins et al further teach their device is primarily used for nucleic acid hybridization (Column 3, lines 7-8) but they do not specifically teach the claimed steps of introducing a liquid sample into the reaction cell. However, the primary use being hybridization clearly suggest doing so. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the device of Robbins et al to hybridization wherein a sample is introduced into their hybridization bottle based on their suggestion of using their device for hybridization.

Robbins et al teach applying rotation force via centrifugation i.e. rotation about an axis (Column 3, lines 43-47). While they do not specifically teach a force in excess of 1G, the claimed force is inherent in the rotational "force" of Robbins. Alternatively, it would have been

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obvious to one of ordinary skill in the art at the time the claimed invention was made to modify rotational force of Robbins et al to obtain a force in excess of 1G based on desired results.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter in which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to “prove that subject matter shown to be in the prior art does not possess characteristic relied on” (205 USPQ 594, second column, first full paragraph).

Regarding Claim 9, Robbins et al teach the agitation involves rotating the cell about an agitation axis that is more orthogonal than along the centrifugal force i.e. angle of agitation is adjustable to obtain desired agitation (Column 7, line 54-Column 8, line 15).

Regarding Claims 10-11, Robbins et al specifically teach adjustment of the agitation based desired application (Column 7, line 54-Column 8, line 22). While they do not specifically teach changing direction of rotation or relative rates of rotation and agitation their teaching of adjustability clearly suggests doing so. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify change the direction and/or rates of rotation and agitation based on the suggestion of Robbins to do so (Column 7, line 54-Column 8, line 22).

Regarding Claim 12, Robbins et al teach the agitation involves rotating the cell about an agitation axis that is more parallel than orthogonal to the centrifugal force i.e. angle of agitation is adjustable to obtain desired agitation (Column 7, line 54-Column 8, line 15).

Regarding Claim 13, Robbins et al teach the method wherein the array (membrane) extends more orthogonal to the force than along it urging the sample against the array (Fig.4).

Regarding Claim 15, Robbins et al illustrate the liquid occupies less than half of the volume (Fig. 4) and they clearly suggest so wherein they teach the agitation provides uniform

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coating and wetting of the membrane while using minimum amount of solution (Column 3, lines 23-30).

Regarding Claim 16, Robbins et al teach a reaction cell (bottle) having a hybridization array (nucleic acid spots on a membrane, Column 3, line 7-10) so that some interior volume is partially occupied by a sample liquid and partially occupied by gas (Fig. 4) wherein centrifugation (via rotational force, column 3, lines 43-47) of the sample liquid is by rotating the reaction cell whereby agitation of the sample during the centrifugation moves the sample relative to the array (Column 3, lines 4-57 and Abstract) wherein the agitation axis is more orthogonal than along the centrifugal force i.e. angle of agitation is adjustable to obtain desired agitation (Column 7, line 54-Column 8, line 15)..

Robbins et al further teach their device is primarily used for nucleic acid hybridization (Column 3, lines 7-8) but they do not specifically teach the claimed steps of introducing a liquid sample into the reaction cell. However, the primary use being hybridization clearly suggests doing so. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the device of Robbins et al to hybridization wherein a sample is introduced into their hybridization bottle based on their suggestion of using their device for hybridization.

Regarding Claims 17-18, Robbins et al specifically teach adjustment of the agitation based desired application (Column 7, line 54-Column 8, line 22). While they do not specifically teach changing direction of rotation or relative rates of rotation and agitation their teaching of adjustability clearly suggests doing so. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify change the direction and/or rates of rotation and agitation based on the suggestion of Robbins to do so (Column 7, line 54-Column 8, line 22).

Regarding Claim 19, Robbins et al illustrate the liquid occupies less than half of the volume (Fig. 4) and they clearly suggest so wherein they teach the agitation provides uniform

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coating and wetting of the membrane while using minimum amount of solution (Column 3, lines 23-30).

Regarding Claim 20, Robbins et al teach a reaction cell (bottle) having a hybridization array (nucleic acid bolts on a membrane, Column 3, line 7-10) so that some interior volume is partially occupied by a sample liquid and partially occupied by gas (Fig. 4) wherein centrifugation (via rotational force, column 3, lines 43-47) of the sample liquid is by rotating the reaction cell whereby agitation of the sample during the centrifugation moves the sample relative to the array (Column 3, lines 4-57 and Abstract) wherein the agitation axis is more parallel than orthogonal to the centrifugal force i.e. angle of agitation is adjustable to obtain desired agitation (Column 7, line 54-Column 8, line 15)..

Robbins et al further teach their device is primarily used for nucleic acid hybridization (Column 3, lines 7-8) but they do not specifically teach the claimed steps of introducing a liquid sample into the reaction cell. However, the primary use being hybridization clearly suggest doing so. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the device of Robbins et al to hybridization wherein a sample is introduced into their hybridization bottle based on their suggestion of using their device for hybridization.

Regarding Claims 21-22, Robbins et al specifically teach adjustment of the agitation based desired application (Column 7, line 54-Column 8, line 22). While they do not specifically teach changing direction of rotation or relative rates of rotation and agitation their teaching of adjustability clearly suggests doing so. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify change the direction and/or rates of rotation and agitation based on the suggestion of Robbins to do so (Column 7, line 54-Column 8, line 22).

Regarding Claim 23, Robbins et al teach the method wherein the array (membrane) extends more orthogonal to the force than along it urging the sample against the array (Fig.4).

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Regarding Claim 25, Robbins et al illustrate the liquid occupies less than half of the volume (Fig. 4) and they clearly suggest so wherein they teach the agitation provides uniform coating and wetting of the membrane while using minimum amount of solution (Column 3, lines 23-30).

8. Claims 14 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robbins et al (U.S. Patent No. 5,380,662, issued 10 January 1995) in view of Trulson et al (U.S. Patent No. 5,834,758, issued 10 November 1998).

Regarding Claims 14 and 24, Robbins et al teach a reaction cell (bottle) having a hybridization array (nucleic acid spots on a membrane, Column 3, line 7-10) so that some interior volume is partially occupied by a sample liquid and partially occupied by gas (Fig. 4) wherein centrifugation (via rotational force, column 3, lines 43-47) of the sample liquid is by rotating the reaction cell whereby agitation of the sample during the centrifugation moves the sample relative to the array (Column 3, lines 4-57 and Abstract). Robbins et al do not teach removal of the sample.

Trulson et al teach a similar array hybridization method comprising introducing a sample liquid into a reaction cell so that some of the interior volume is partially occupied by sample liquid and partially occupied by gas (N₂ bubbles) and agitating said sample liquid in the reaction cell during centrifugation so that said sample liquid moves relative to the array (Column 9, line 27-50 and Column 14, lines 12-42) and further comprising removing sample liquid from the reaction cell wherein removing the liquid involves rotating (agitating using injected N₂) to force fluid away from the array (Column 14, lines 12-60). Trulson et al further teach the agitation system effectively moves fluids into and out of the reaction cell (Column 9, lines 37-40 and Column 14, lines 36-40).

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the sample removal of Trulson et al to the hybridization device of Robbins for the expected benefit of efficient fluid movement into and out of the reaction cell as illustrated by Trulson et al (Column 9, lines 37-40 and Column 14, lines 36-40).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 8-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 09/729,169. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods comprising the steps of introducing a liquid into a reaction cell, centrifuging the sample by rotating the cell and agitating (mixing) the sample. The sets of claims differ only in the arrangement of limitations. For example, instant Claim 1 is drawn to an array hybridization method while Claim 1 of the '169 application is drawn to a method for contacting components

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and dependent Claim 12 limits the method to hybridization. As such, both sets of claims are drawn to similar methods which are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

11. Applicant intention to file a Terminal Disclaimer upon indication of allowable subject matter is acknowledged. The rejection is maintained.

12. Claim 8 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 51 of copending Application No. 09/900,294. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to methods of hybridization comprising the steps of introducing a liquid into a reaction cell and maintaining conditions within the reaction cell to obtain hybridization. The sets of claims differ only in that the instant claim recites the hybridization condition (i.e. centrifuging the sample by rotating the cell and agitating the sample) while the '294 application relies on the disclosure to define identical conditions (i.e. centrifuging the sample by rotating the cell and agitating the sample, ¶ 82-84). As such, both claims are drawn to similar methods which are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

13. Applicant intention to file a Terminal Disclaimer upon indication of allowable subject matter is acknowledged. The rejection is maintained.

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Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
July 30, 2004